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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

EPPERSON, JON D

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 05/23/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,746

Applicant(s)

SCHMIDT ET AL.

Examiner

Jon D Epperson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

SUBSTITUTE RESTRICTION

Please note: In preparing this Restriction Requirement the Examiner noted a problem with many of the claim dependencies e.g., claim 12 states “[a] method according to claim 12” i.e., the claim improperly depends on itself (please note that there are many mistakes throughout the claims). The Examiner has interpreted this and all of the other improperly dependent claims to be dependent on the preceding claims only. It would greatly assist prosecution for Applicants to address and/or correct these issues.

Please Note: There is a change in Examiner handling prosecution in the current case from Examiner Samuel A. Barts to Jon D. Epperson.

1. Upon further review of applicant’s claims and in view of applicants’ arguments (see Paper No. 8), all previous restriction and election of species requirements are hereby withdrawn and the substitute restriction and election of species is now required (see below).

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-34, drawn to a method for characterizing an analyte.
 - II. Claims 35-39, drawn to a product described as a compound having the formula presented in claim 35.
3. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons that follow.

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4. PCT Rule 13.2 states that unity of invention shall be fulfilled when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.” It further defines “special technical feature” as “those technical features that define a contribution which each of the claimed inventions, claimed as a whole, makes over the prior art.”

5. The technical feature that links all of the claims are the compounds presented by the formula in claim 1. The groups lack unity because this technical feature is known in the art as disclosed by Cittanova et al (FR 2 574 184 – A1) (Date of Publication is June 6, 1986). This reference is described below.

6. Cittanova et al (see entire document) discloses compounds of formula II (see page 7, English translation) with Z = the compound shown on the bottom of page 23 that eventually becomes covalently bound through the nitrogen to testosterone-3 CMO (see top of page 24). In this scenario, R is the disulfanato-3,6 naphthalimide, R' is the testosterone-3 and the linker is the compound shown on the bottom of page 23 wherein $SO_n = SO_2$.

7. Therefore, the technical feature linking the inventions of groups I-II does not constitute a species technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Groups I-II are different in that the special technical feature of Group I is drawn to a method of using compounds with the formula presented in claim 1. The special technical feature of Group II is drawn to compounds of the formula presented in claim 35.

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8. Accordingly, groups I-II are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

9. Finally, see 37 CFR § 1.475 - Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage, cited in part below (especially sections (c) and (d)).

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression special technical features shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

A product and a process specially adapted for the manufacture of said product;

or

A product and process of use of said product; or

A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

A process and an apparatus or means specifically designed for carrying out the said process; or

A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

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10. Groups I-II represent product and process of using. However, the technical feature that links the claims (the compounds with the formula presented in claim 1) is known in the art, as set forth above. Thus, the instant claims lack unity of invention.

Species Election

11. This application contains claims directed to more than one species of the generic invention for Groups I-II. These species are deemed to lack unity of invention because they are not so linked to form a single general inventive concept under PCT Rule 13.1.

12. If applicant elects the invention of Groups I applicant is required to elect from the following patentably distinct species. Claim 1 is generic. Applicant must elect 1 species from each subgroup below.

Subgroup 1: Species of compound (e.g., see claims 1,11)

Applicant must elect for purposes of search a single species of compound shown in claim 1. Furthermore, applicant must show all atoms and bonds that are necessary to define said compound. Applicant should NOT use general notations like X-Handle, R₁, Handle, n, and X', etc. when defining the structure because these labels represent more than one chemical group and thus more than one compound would be erroneously elected. **Please note:** applicants must show all bonds and atoms of the compound including the "analyte" and "reporter" and any and all connectivity thereto. Applicant must also indicate where the cleavable site is within the linker. This would also include any metals that are attached to the compound e.g., Ni²⁺, Li⁺, etc. (see claim 29).

Subgroup 2: Species of cleaving (see claim 1)

Applicant must elect, for the purposes of search, a single species of method for cleaving the reporter group from the analyte.

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Subgroup 3: Species of method for identifying the reporter (see claim 1)

Applicant must elect, for the purposes of search, a single species of method for identifying the reporter e.g., mass spectrometry.

13. If applicant elects the invention of Groups II applicant is required to elect from the following patentably distinct species. Claim 35 is generic. Applicant must elect 1 species from each subgroup below.

Subgroup 1: Species of compound (see claim 35)

Applicant must elect for purposes of search a single species of compound shown in claim 35. Furthermore, applicant must show all atoms and bonds that are necessary to define said compound. Applicant should NOT use general notations like X-Handle, R₁, Handle and X', etc. when defining the structure because these labels represent more than one chemical group and thus more than one compound would be erroneously elected.

14. **Please Note:** Applicants **MUST** disclose which claims read on the elected species (see paragraphs 19 and 20 below).

15. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons.

16. PCT Rule 13.2 states that unity of invention shall be fulfilled when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features". It further defines "special technical feature" as "those technical features that

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define a contribution which each of the claimed inventions, claimed as a whole, makes over the prior art". For example, unity of invention is fulfilled if:

- (a) all alternatives have a common property; **and**
- (b) (i) a common structure is present, i. e. a significant structural element is shared by all alternatives, or
- (b) (ii) in cases where the common structure can not be the unifying criterion, all alternatives belong to a recognized class of compounds in the art to which the invention pertains. (MPEP 1850).

17. In the instant case, the molecules in subgroup 1 do not have a common property or common structure. In the case of subgroups 2-3 the methods do not have a common property. Consequently, the group as a whole does not share a common structure and/or a common property and, as a result, do not meet the requirements of PCT Rule 13.2.

For these reasons, election under these rules is proper and required.

18. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

19. Applicant is advised that a reply to this requirement **must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.** An argument that a claim is allowable or that all claims are generic is considered **nonresponsive** unless accompanied by an election.

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20. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, *applicant must indicate which are readable upon the elected species*. MPEP § 809.02(a).

21. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

22. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

23. Applicant is also reminded that a 1 - month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

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Conclusion

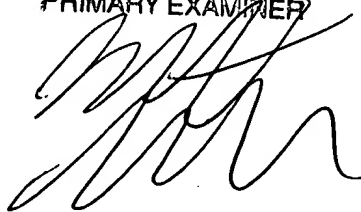
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (703) 308-2423. The examiner can normally be reached Monday through Friday from 8:30 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-2439.

Jon D. Epperson, Ph.D.
May 20, 2003

BENNETT CELSA
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to be 'B. Celsa', written over the printed name and title.